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09/762,779	07/03/2001	Johannes Gijsbertus Antonius Terlingen	702-010166	7918

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

J/C

Office Action Summary

Application No.

09/762,779

Applicant(s)

TERLINGEN ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25 and 29-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25 and 29-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

The amendment filed December 28, 2004 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 44 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 is vague and indefinite because the claim is directed to a method for investigating the interaction of pre-determined chemical or biological species and does not set forth the steps involved in performing the analyzing. For example, there are not steps of contacting interactive species, binding of species or detection of the interaction. Further, the recitation "the interaction between chemical or biological species arranged on the device" is vague and indefinite because it is unclear if applicant is referring to the sulfur that has been deposited on the substrate or if applicant is referring to a sample containing a chemical or biological species which binds to the sulfur and is subsequently detected with another molecule or does the substrate comprise both a sulfur deposit and a chemical or biological species other than the sulfur or is applicant referring to something else? Please clarify.

Claim 45 is vague and indefinite because the preamble of the claim is directed toward a method. However, no method steps have been provided for performing the

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process. For example, there are not steps of contacting interactive species, binding of species or detection of the interaction. Further, the amended recitation "comprising the step of exposing or depositing chemical or biological species" is vague and indefinite because it is unclear what applicant is referring to. Is applicant referring to the sulfur that has been deposited on the substrate or is applicant referring to a sample containing a chemical or biological species which binds to the sulfur and is subsequently detected with another molecule or is applicant referring to something else? Please clarify.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 25, 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergstrom et al (WO 90/05303).

Bergstrom et al disclose a device comprised of a substrate (p 13, lines 13-21). Bergstrom et al disclose that a film of a free electron metal of gold is applied to the substrate (p. 5, lines 29-38). Bergstrom et al disclose that the gold surfaces are modified by sulfur compounds (p. 6, lines 4-30). Bergstrom et al disclose that the sulfur compounds have a high affinity for the metal (p. 4, lines 26-30) and that the sulfur binds to the gold metal film (p. 6). Bergstrom et al disclose that the sulfur compounds can be coupled to functional groups.

With respect to the deposited plasma and plasma deposited as recited in the instant claims. The claims are directed to a product and the patentability does not depend on its method of production (plasma deposited). Thus it is irrelevant how the device was produced. The teachings of Bergstrom et al disclose the same device as recited in the instant claims therefore, Bergstrom et al anticipates the instantly recited claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 25, 29-31, 33, 37-45, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al (EP 0104608) in view of Bergstrom et al (WO 90/05303).

Dunn et al disclose a method and apparatus for modifying the surface chemistry of a substrate. Dunn et al teach that the attachment and orientation of biologically active molecules can be controlled by varying the surface chemistry of a metal substrate surface by using plasma modification techniques which yield a range of surface chemistries and properties (page 4, lines 1-9). Dunn et al teach that these modified polymeric surfaces were subjected to solutions of biologically active molecules and subsequently tested to demonstrate that attachment and orientation of the large molecule is highly dependent on surface chemistry (page 4, lines 10-16). Dunn et al also teach that the surface of the substrate is irreversibly modified by grafting specific chemical functional groups onto the surface with a plasma of suitable material such as sulfur (page 5, lines 1-25). Dunn et al teach that plasmas can be generated by use of DC or AC sources having a frequency of about 1.0W to about 10 kw. Dunn et al also teach the use of radio frequency (r.f.) sources to generate plasmas (page 9, lines 14-30). Dunn et al disclose that r.f. plasmas are generated at a frequency of from about 1.0 to about 300 MHz at a power to initiate breakdown, such as from about 5 to about 1000 watts at pressures ranging from 0.001 to 10 Torr. The articles are subjected to the

r.f. plasma for a period of about 0.1 seconds to about 120 minutes and the plasma treatment can be followed by a quench cycle at or near the surface with pressures ranging from 1 Torr to 760 Torr for time periods of 1 second to 4 hours (page 10, lines 6-19).

Dunn et al differ from the instant invention in failing to teach the substrate comprising a film of gold. Dunn et al also differ from the instant invention in failing to teach a bio/chemical functional layer is wet chemically arranged on the plasma deposited first functional group species layer.

Bergstrom et al disclose a substrate comprising a film of a free electron metal of gold. Bergstrom et al disclose that the gold surfaces are modified by sulfur compounds (p. 6, lines 4-30). Bergstrom et al disclose that the sulfur compounds have a high affinity for the metal (p. 4, lines 26-30) and that the sulfur binds to the gold metal film (p. 6). Bergstrom et al disclose that the sulfur compounds can be coupled to functional groups. Bergstrom et al disclose that gold is a preferred metal layer because of corrosion stability considerations (p. 5, lines 29-34). Bergstrom et al disclose applying a hydrogel to the first functional group and discloses that this hydrogel provides specificity for a second functional group species (p. 8-9). Bergstrom discloses that the hydrogel provides for the minimization of undesired interactions (p. 9).

It would have been obvious to one of ordinary skill in the art to incorporate the use of a gold film as taught by Bergstrom et al into the method and apparatus of Dunn et al because Bergstrom et al teaches that gold provides for a more stable metal surface because of corrosion stability considerations.

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It would have also been obvious to one of ordinary skill in the art to incorporate a hydrogel as taught by Bergstrom et al into the method and device of Dunn et al because Bergstrom et al teaches that this hydrogel provides for the minimization of undesired interactions.

With respect to the conditions for gas plasma deposition recited in the instant claims, the optimum conditions for discharge power, exposure duration, plasma gas flow, pressure and frequency can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

9. Claim 32 , 34, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al and Bergstrom et al in view of Tarlov et al (US

See above for the teachings of Dunn et al and Bergstrom et al.

Dunn et al and Bergstrom et al differ from the instant invention in failing to teach the substrate consists essentially of gold.

Tarlov et al disclose a substrate consisting essentially of gold which has bound to its surface sulfur compounds.

It would have been obvious to one of ordinary skill in the art to incorporate a substrate consisting essentially of gold as taught by Tarlov et al for the modified gold substrate of Dunn et al because Dunn et al and Bergstrom et al teach gold coated substrates having sulfur compounds bound on its surface and Tarlov teaches the substrate made of gold in which sulfur compounds are bound to the gold substrate. Therefore, one skilled in the art would have a reasonable expectation of success utilizing a substrate consisting essentially of gold.

10. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al and Bergstrom et al in view of Kolluri et al (US 5,723,219).

See above for teachings of Dunn et al and Bergstrom et al.

Dunn et al and Bergstrom et al differ from the instant invention in failing to disclose that plasma is deposited from a monomer in gas form.

Kolluri et al teaches the use of a gas monomer in plasma polymerization techniques. Kolluri et al teach that the use of these monomers allow for the determination of a desired surface chemistry (col 5, lines 31-39).

It would have been obvious to one of ordinary skill in the art to incorporate the monomer as taught by Kolluri into the method of Dunn et al as modified by Bergstrom et al because Kolluri et al shows that the use of these monomers allow for the determination of a desired surface chemistry.

11. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al and Bergstrom et al in view of Sluka et al (US 5,932,296).

See above for teachings of Dunn et al and Bergstrom et al.

Dunn et al and Bergstrom et al differ from the instant invention in failing to teach the cleaning of the substrate.

Sluka et al teach the step of cleaning the substrate by means of a pulsed argon plasma before the application of the functional groups to the substrate (col 3, lines 21-24). This process would allow for the removal of any possible surface contamination and allow the surface to be specifically furnished with specific binding sites which are capable of binding directly to an analyte or specific binding partner of interest (col 4, lines 13-15).

It would have been obvious to one of ordinary skill in the art to incorporate the cleaning step as taught by Sluka et al into the method of Dunn et al as modified by Bergstrom et al because Sluka et al shows that this allows the surface to be specifically furnished with specific binding sites which are capable of binding directly to an analyte or specific binding partner of interest.

Response to Arguments

12. Applicant's arguments filed December 28, 2004 have been fully considered but they are not persuasive.

112 2nd rejection arguments

Applicant argues that claim 44 has been amended to include the step of analyzing the interaction between chemical or biological species and that the techniques used for "analyzing" are disclosed on page 1, lines 9-21 of the present specification and that because the step of "analyzing" in claim 44 is defined clearly in

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the specification, the techniques used for performing the analyzing does not need to be included in claim 44. This is not found persuasive for the following reasons: 1) the amended claim raises new 112 2nd rejections because it is unclear if applicant is referring to the sulfur that has been deposited on the substrate or if applicant is referring to a sample containing a chemical or biological species which binds to the sulfur and is subsequently detected with another molecule or does the substrate a both a sulfur deposit and a chemical or biological species other than the sulfur or is applicant referring to something else? (see 112 2nd rejection above), and (2) Although, the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Thus, the claims are vague and indefinite and cannot stand on their own merits.

Applicant argues that claim 45 has been amended to include the step of exposing or depositing chemical or biological species on the device. This is not found persuasive because the amended claims provide further 112 2nd rejections (see above 112 2nd rejections).

102 rejection arguments

Applicant argues that the plasma phase consists of a wide variety of very reactive species, the final composition of a surface after treatment with a plasma is essentially disordered and unpredictable and does not have the same chemical composition as the gas that was originally used and therefore the sulfur plasma layer of the present invention is a completely different layer having substantially different properties from the

self-assembled monolayer disclosed in the Bergstrom patent. This is not found persuasive because the deposited plasma and plasma deposited as recited are directed to a product and the patentability does not depend on its method of production (plasma deposited). The end result would be sulfur deposited on the gold film of the substrate and regardless how the sulfur is applied is irrelevant. Further, with respect to applicants statement that the deposited material has different properties than that of Bergstrom, this is not found persuasive because the claim recites comprising language directed to the gold film and therefore the gold film which binds to the sulfur can also have other components on it therefore, it reads on the instantly recited claims. Therefore, the teachings of Bergstrom et al disclose the same device as recited in the instant claims therefore, Bergstrom et al anticipates the instantly recited claims.

103 rejection arguments

The Applicant states that "the examiner contends that the motivation to use gold as a substrate in the Dunn patent comes from the fact that gold is highly resistant to corrosion as disclosed in the Bergstrom patent. Gold is a rare, noble metal that is known for its resistance to oxidation and corrosion. A noble metal is defined as any metal that is resistant to corrosion or oxidation and includes gold, silver and platinum. Silver and platinum also exhibit corrosion resistant properties similar to gold". Applicant argues that the list of metals disclosed in the Dunn patent does not include silver and platinum and when considering the Dunn patent in its entirety, wherein polystyrene substrate and the list of metal substrates does not disclose any of the noble metals, the Dunn patent directs away from the use of highly corrosion resistant noble metals as a

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substrate for plasma deposition. This is not found persuasive because when considering the Dunn et al patent in its entirety, Dunn et al specifically teaches the substrate can be metals such as aluminum or copper and Bergstrom et al specifically teaches that substrates can be copper, aluminum or gold and specifically teaches the advantages of using gold over copper and aluminum (two stances clearly taught by Dunn et al). Therefore, the combination of Dunn et al and Bergstrom et al is maintained for reasons stated above and in the previous office action and further because Bergstrom et al specifically teaches the advantage of gold over copper and aluminum (two substances clearly taught by Dunn et al.). Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating the use of gold film as taught by Bergstrom et al into the method and apparatus of Dunn et al.

Applicant argues that the Bergstrom patent requires a particular orientation of the organic molecule X-R-Y to the metal surface and because of the nature of a plasma, the specific type of orientation required in the process of the Bergstrom patent could not be achieved using plasma, thereby destroying the intended function of the attachment process in the Bergstrom patent. This is not found persuasive because Examiner has not relied upon Bergstrom et al for the process, but rather has relied upon Bergstrom et al for teachings that it is known in the art to use gold as metal surface with sulfur deposited directly on the gold and for teaching the advantages of using a gold surface, and also for teaching the advantages of wet chemically deposited layers.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

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any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

With respect to the arguments directed toward Tarlov et al, Kolluri et al and Sluka et al. Applicant argues that because the teachings of Dunn et al and Bergstrom et al are allowable and therefore the rejections of dependent claims by Tarlov et al., Kolluri et al. and Sluka et al are allowable. This is not found persuasive because as stated above the rejections of Dunn et al and Bergstrom et al are maintained and therefore the combination with Tarlov et al, Kolluri et al and Sluka et al., are considered appropriate and are maintained also.

Conclusion

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

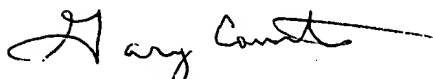
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts
Examiner
Art Unit 1641
March 17, 2005



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03/17/05